UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,407	04/22/2005	Adel Penhasi	030231-0158	9132

22428 7590 02/20/2009

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,407	PENHASI ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 102* is/are pending in the application.

4a) Of the above claim(s) *1 - 88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89 - 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed December 8, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Terminal Disclaimer

1. The terminal disclaimer filed on December 8, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,703,044 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 89, 91 and 93 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 45 and 47 – 49 of copending Application No. 10/555310 in view of US Patent 5,840,332. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed June 9, 2008 and those set forth below.

Applicants have not argued the merits of the rejection but ask that it be withdrawn inasmuch as this is a provisional rejection.

As no indication of allowable subject matter has been made in this case which is, at this time, further along in prosecution than the co-pending case, this rejection will not be withdrawn. The functional limitation regarding the absence of venlafaxine release added to the claims of the instant application have not patentably distinguished the claims of this application over the claims of '310. The release profile of the venlafaxine is determined by the physical structure and components of the pharmaceutical preparation. The claims of both applications recite a venlafaxine dosage form with the same components – a core comprising venlafaxine, microcrystalline cellulose, which reads on filler and burst controlling agent, and water soluble cellulosic polymers, which reads on the disintegrant of the instant claims and a coating comprising a water insoluble hydrophobic carrier and a water-insoluble but hydrophilic particulate matter. Therefore, the limitations regarding the release profile of the venlafaxine must be inherently met as both the instant claims and the claims of '310 recite venlafaxine formulations with the same physical structure and components.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 89 – 102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Functional limitations regarding the release characteristics of the dosage form have been added, namely that substantially no venlafaxine is released *in vitro* for at least about two hours and also that after the delayed burst release occurs, at least about 60% of the venlafaxine is release in about 1 hour after the burst release. The data presented in figures 14a, 14b, 15a and 15b meet these functional limitations but there is no indication of which formulations presented in the specification provide these release profiles. B.N. numbers are given but these numbers do not correspond to the identifiers used in the examples presented in the specification and it appears, but is not stated, that the data shown #1 - #6 are for separate dosage forms with the same composition. The specification provides insufficient written description to support the genus of all venlafaxine formulations which provide the required release profiles of the active ingredient as Applicant has not provided any examples or description which links the release characteristics of the formulation to the physical composition of the formulations.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 89 – 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 89, 91 and 93 contain the limitation "at least about two hours". "At least" indicates a minima and all possible values above two hours are encompasses. "About" indicates a range centered on the recited values. Therefore, what values are included in the range "at least about two hours" cannot be determined.

8. Claims 89 – 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 89, 91 and 93 contain the limitation "said formulation releases substantially no venlafaxine". "Substantially no" is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if no drug can be released during this time, as occurs with the formulations in figures 14a, 14b, 15a and 15b which are described using this same phrase or if some small, undefined amount of venlafaxine can be released within the specified time frame and the limitations present in the claims would still be met.

9. Claims 97 – 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim contains the limitation "at least about 60%". "At least" indicates a minima and all possible values above 60% are encompasses. "About" indicates a range centered on the recited values. Therefore, what values are included in the range "at least about 60%" cannot be determined.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 89 – 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (US 6,274,171) in view of Lerner et al. (US 5840,332). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed June 9, 2008 and those set forth below. This rejection is now applied to new claims 89 – 99.

Applicant traverses this rejection on the grounds that Lerner neither describes nor provides a foundation for use of his described formulation of venlafaxine or for formulation of active ingredients useful in treating depression. Sherman describes extended release formulation but does not describe a formulation allowing for delayed burst release. As described in example 11, Applicants have found unexpectedly that the specific formulation utilized is bioequivalent to the extended release formulation at a significantly lower dose (60 vs 75 mg).

These arguments are not found to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., bioequivalence to a 75 mg extended release formulation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The release profile of the venlafaxine is determined by the physical structure and components of the pharmaceutical preparation. The combination of the cited prior art discloses coated core venlafaxine formulations with a core comprising venlafaxine, at least one burst controlling agent and a disintegrant with the outer coating comprised of a water insoluble hydrophobic carrier and a water-insoluble but hydrophilic particulate matter. The claims of the instant application recite a coated core venlafaxine formulation with a core comprising venlafaxine, at least one burst controlling agent and a disintegrant with the outer coating comprised of a water insoluble hydrophobic carrier and a water-insoluble but hydrophilic particulate matter. Therefore, the limitations regarding venlafaxine release (substantially no release for at least about 2 hours, a burst release after at least about 2 hours and at least about 60% of the venlafaxine release within about 1 hour of the delayed burst release occurring) must be inherently met as both the instant claims and the cited prior art recite a coated core venlafaxine formulation with a core comprising venlafaxine, at least one burst controlling agent and a disintegrant with the outer coating comprised of a water insoluble hydrophobic carrier and a water-insoluble but hydrophilic particulate matter.

Also, the release profile of the active substance is a results effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary

for an artisan of ordinary skill to determine the optimal release profile for the venlafaxine in order to best achieve the desired results.

14. Claims 89 – 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. and Sherman et al. as applied to claims 89 – 99 above, and further in view of Upton et al. (US 5,506,270).

As discussed above, Lerner et al. and Sherman et al. disclose a coated core venlafaxine formulation with a core comprising venlafaxine, at least one burst controlling agent and a disintegrant with the outer coating comprised of a water insoluble hydrophobic carrier and a water-insoluble but hydrophilic particulate matter.

Neither reference discloses a venlafaxine dosage of 60 mg.

Upton et al. discloses that the usual recommended oral dosage of venlafaxine for human is between about 25 mg/day and about 200 mg/day (col 4, ln 67 – col 5, ln 4) and the dosage will be determined by the particular circumstances regarding each case (col 5, ln 13 – 17).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a dosage form as disclosed by Lerner et al. and Sherman et al. One of ordinary skill would be motivated and reasonably would have expected success as Lerner et al. and Upton et al. both relate to oral dosage forms of venlafaxine. The amount of active ingredient in a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a

person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of active ingredient to add in order to best achieve the desired results. The amount of venlafaxine will be dependent on a variety of factors, including the dosing frequency, the particular condition being treated and that severity of the condition for a particular patient.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW